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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.

09/965,426

Confirmation No. 4436

Applicant

Gary R. DelDuca *et al*. September 27, 2001

Filed Title

MODIFIED ATMOSPHERIC PACKAGES AND

METHODS FOR MAKING THE SAME

TC/A.U.

1761

Examiner

Jyoti Chawla

Docket No.

247097-001106USC1

TRANSMITTAL OF REVISED APPEAL BRIEF

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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Julie Burke

In response to the Notice of Non-Compliant Appeal Brief dated August 14, 2007, the Appellants are filing a Revised Appeal Brief. No amount is believed to be due. Please charge any fees (except the issue fee) or credit any additional fees to Deposit Account 50-4181 (Attorney Docket No. 247097-001106USC1).

Date: August 31, 2007

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09/956,426

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Applicant

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1761

Examiner

: Jyoti Chawla

Docket No.

247097-001106USC1

REVISED APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 **CERTIFICATE OF MAILING**

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August 31, 2007

Signature:

Julie Burke

Dear Commissioner:

This revised appeal brief is filed pursuant to Notification of Non-Compliant Appeal Brief dated August 14, 2007. Appellants' appeal to the Board of Patent Appeals and Interferences is from the final rejection of claims 38-56, 76-86 and 119-168 in an Office Action dated February 23, 2007, for the above-listed application.

1. REAL PARTY IN INTEREST

The real party in interest is Pactiv Corporation, a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1900 West Field Court, Lake Forest, IL 60045.

2. RELATED APPEALS AND INTERFERENCES

This appeal is related to the appeal filed in Application No. 10/190,375. The Notice of Appeal was filed on February 6, 2007 and the corresponding appeal brief was filed on April 6,

2007. This appeal is also related to the appeal filed in Application No. 09/915,150. The Notice of Appeal was filed on May 8, 2007 and the corresponding appeal brief was filed on May 18, 2007. There are no other related appeals and interferences.

3. <u>STATUS OF CLAIMS</u>

Claims 38-56, 76-86 and 119-168 are pending and have been finally rejected. The Appellants note that dependent claims 122, 141 and 160 have been previously withdrawn but are still pending the application. It is from the final rejection of claims 38-56, 76-86 and 119-168 that this appeal is taken.

Claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159 and 161-168 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,686,127 to Stockley ("Stockley") in view of U.S. Patent No. 3,459,117 to Koch ("Koch"); U.S. Patent No. 4,522,835 to Woodruff ("Woodruff"); and U.S. Patent No. 6,042,859 to Shaklai ("Shaklai"). Claims 39, 77, 120, 139 and 158 stand rejected over Stockley in view of Koch, Woodruff, Shaklai and U.S. Patent No. 5,629,060 to Garwood ("Garwood").

4. STATUS OF AMENDMENTS

A Final Office Action was mailed on February 23, 2007. A Reply to Final Office Action Dated February 23, 2007 was filed with the Patent Office by Appellants on May 23, 2007, but no amendments were made. The Notice of Appeal was also filed in this patent application on May 23, 2007. In response, the Examiner issued an Advisory Action on June 18, 2007, in which the § 112, first paragraph, rejections were withdrawn and the § 103 rejections were maintained.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a method of manufacturing a modified atmosphere package and also to the modified atmosphere package (e.g., 110, 210, 310; FIGS. 8, 8A, 9B; page 13, line 18-page 14, line 29). The independent method claims (claims 38, 119 and 138) comprise supplying a package (e.g., 116; FIG. 8), a first layer (e.g., 121; FIG. 8; page 14, lines 1-4) having at least a portion being substantially permeable to oxygen and a second layer (e.g., 123; FIG. 8; page 14, lines 5-11) being substantially impermeable to oxygen. A retail cut of raw meat (e.g., 126; FIG. 8) is placed within the package (e.g., 116; FIG. 8) and the meat (e.g., 126; FIG. 8) has meat pigment. A mixture of gases is supplied within the package (e.g., 116; FIG. 8)

with the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment (page 20, lines 20-21; page 4, lines 19-22; page 17, lines 21-23) so as to form carboxymyoglobin on a surface of the raw meat (e.g., 126; FIG. 8; page 10, lines 9-25-page 11, line 1). Oxygen is removed within the package (e.g., 116; FIG. 8; page 10, lines 17-30) so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat (e.g., 126; FIG. 8). The first layer (e.g., 121; FIG. 8) is sealed to the package (e.g., 116; FIG. 8; page 14, lines 5-6). The second layer (e.g., 123; FIG. 8) is sealed to at least one of the group consisting of the package (e.g., 116; FIG. 8) and the first layer (e.g., 121; FIG. 8; page 5, lines 30-32).

Independent claim 38 further recites the second layer (e.g., 123; FIG. 8) being adapted to be removed such that the second layer (e.g., 123; FIG. 8) is no longer sealed to the package (e.g., 116; FIG. 8) or the first layer (e.g., 121; FIG. 8; page 14, lines 1-4), the first layer (e.g., 121; FIG. 8; page 14, lines 1-4) remains sealed to the package (e.g., 116; FIG. 8), and wherein the carbon monoxide associated with the raw meat (e.g., 126; FIG. 8) is adapted to be removable after the second layer (e.g., 123; FIG. 8; page 12, lines 2-12) is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer (e.g., 121; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application). Independent claim 119 further recites opening the package (e.g., 116; FIG. 8) such that the raw meat (e.g., 126; FIG. 8) is allowed to be exposed to the ambient atmosphere and the carbon monoxide associated with the raw meat (e.g., 126; FIG. 8) is adapted to be removable (e.g., page 12, lines 2-12) such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package (e.g., 116; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application). Independent claim 138 further recites opening the package (e.g., 116; FIG. 8) before retail display such that the gas mixture exits the package (e.g., 116; FIG. 8) and the carbon monoxide associated with the raw meat (e.g., 126; FIG. 8) is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package (e.g., 116; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application; page 12, lines 2-12).

The independent modified atmosphere package claims (claims 76 and 157) comprise a package (e.g., 116; FIG. 8) being configured and sized to fully enclose a retail cut of raw meat

(e.g., 126; FIG. 8), a first layer (e.g., 121; FIG. 8; page 14, lines 1-4) and a second layer (e.g., 123; FIG. 8; page 14, lines 5-11). The meat (e.g., 126; FIG. 8) has meat pigment and the package (e.g., 116; FIG. 8) has a mixture of gases comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment (e.g., page 20, lines 20-21; page 4, lines 19-22; page 17, lines 21-23) so as to form carboxymyoglobin on a surface of the raw meat (e.g., 116; FIG. 8). The first layer (e.g., 121; FIG. 8; page 14, lines 1-4) has at least a portion being substantially permeable to oxygen and sealed to the package (e.g., 116; FIG. 8). The second layer (e.g., 123; FIG. 8; page 14, lines 5-11) is substantially impermeable to oxygen and sealed to at least one of the group consisting of the package (e.g., 116; FIG. 8) and the first layer (e.g., 121; FIG. 8; page 5, lines 30-32; page 14, lines 1-4).

Independent claim 76 further recites the second layer (e.g., 123; FIG. 8; page 14, lines 5-11) being adapted to be removed such that the second layer (e.g., 123; FIG. 8) is no longer sealed to the package (e.g., 116; FIG. 8) or the first layer (e.g., 121; FIG. 8; page 14, lines 1-4), and the first layer (e.g., 121; FIG. 8; page 14, lines 1-4) remains sealed to the package (e.g., 116; FIG. 8), and wherein the carbon monoxide associated with the raw meat (e.g., 116; FIG. 8) is adapted to be removable after the second layer (e.g., 121; FIG. 8; page 14, lines 1-4) is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer (e.g., 123; FIG. 8; page 14, lines 1-4; page 12, lines 2-11, page 21, lines 20-29; examples of the present application). Independent claim 157 further recites wherein the package (e.g., 110; FIG. 8) is adapted to be opened such that the raw meat (e.g., 116; FIG. 8) is allowed to be exposed to the ambient atmosphere and wherein the carbon monoxide associated with the raw meat (e.g., 116; FIG. 8) is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package (e.g., 110; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- I. Claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159 and 161-168 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,686,127 to Stockley in view of U.S. Patent No. 3,459,117 to Koch; U.S. Patent No. 4,522,835 to Woodruff; U.S. Patent No. 6,042,859 to Shaklai.
- II. Dependent claims 39, 77, 120, 139 and 158 are rejected under § 103 as being obvious over U.S. Patent No. 5,686,127 to Stockley in view of U.S. Patent No. 3,459,117 to Koch; U.S. Patent No. 4,522,835 to Woodruff; U.S. Patent No. 6,042,859 to Shaklai and further in view of U.S. Patent No. 5,629,060 to Garwood.

7. **ARGUMENT**

The Appellants will discuss (1) the present invention, (2) the general case law of obviousness, (3) the reasons why a *prima facie* case has not been satisfied by the obviousness rejections and (4) additional evidence on why the pending claims are not obvious. To assist in explaining the present invention and showing the non-obviousness of the invention, the Appellants previously submitted evidence in the form of several 37 C.F.R. §1.132 declarations by (a) one of the co-inventors Mr. Gary R. DelDuca (Exhibits 1-4)¹; and (b) one skilled in the art of meat processing using modified atmosphere packaging -- Dr. Melvin C. Hunt ("the Hunt Declaration")² (Exhibit 5).

I. Present Invention

The modified atmosphere packages and the methods of manufacturing the same have several advantages: (a) the "seasoning" period of the raw meat may be reduced or eliminated; (b) the ability to obtain consistent blooming with cuts off pigment-sensitive meats (e.g., round bone) is improved; and (c) the ability to avoid "fixing" the color of the meat pigment to red. See, e.g.,

¹ The DelDuca declarations were respectfully submitted as exhibits in the Amendment and Response to Office Action Dated May 7, 2003; Amendment and Response to Office Action Dated June 14, 2004; Amendment and Response to Final Office Action Dated August 12, 2005; and Amendment and Response to Office Action Dated February 24, 2006.

The Hunt Declaration was submitted in this pending application as an exhibit in the Amendment and Response to Office Action Dated June 14, 2004.

page 11, line 29 – page 12, line 15; page 13, lines 11-17 of the application; DelDuca Decl. \P 4 (Exhibit 1).

The "seasoning" period is the time period needed to diffuse the oxygen so that the meat has the ability to fully bloom. Page 3, lines 17-19 of the application; DelDuca Decl. ¶ 5. Trays, such as polystyrene foam trays, have a substantial amount of oxygen contained in its cellular structure that results in a time period of as long as about 5 to about 6 days to diffuse the oxygen contained in its cellular structure. Page 3, lines 21-23 of the application; DelDuca Decl. ¶ 5. If a foam tray is not used, the "seasoning" period can be reduced to one or two days. Page 3, lines 24-25 of the application; DelDuca Decl. ¶ 5. The reduction or elimination of the seasoning period "allows the meat to be displayed for retail sale much sooner than in existing low oxygen packaging systems." Page 11, line 29 – page 12, line 2 of the application; DelDuca Decl. ¶ 5. Seasoning periods are not desired by the retailers or packers because of the "need to store and maintain the meat-filled packages for an extended duration before being opened for retail sale." Page 3, lines 25-28 of the application; DelDuca Decl. ¶ 5.

One important aspect of the present invention is that the present invention does not "fix" the color of the meat pigment to red with its use of carbon monoxide (CO), but rather the meat pigment tends to turn brown in a natural time period after removal of the second layer that is substantially impermeable to oxygen or the opening of the package. See page 12, lines 2-12 of the application; DelDuca Third Decl. ¶ 3 (Exhibit 3). It is important to prevent the meat color from being "fixed" because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. See DelDuca Third Decl. ¶ 3 (Exhibit 3). The term "fix" in this context does not mean that the color of meat pigment never changes to a brown color, but rather that the meat pigment does not turn brown in a natural time period after the meat pigment is exposed to atmosphere. *Id*.

The present invention "surprisingly allows the meat pigment to convert to metmyoglobin in a similar fashion as fresh, raw meat in a retail environment." Page 12, lines 7-10 of the application; DelDuca Decl. ¶ 7 (Exhibit 1). Specifically, the color of the meat pigment after exposure to ambient temperature degrades in a fashion that is not beyond the point of microbial soundness, as if the CO had never been added to the modified packaging system. *Id*.

The meat used in the modified atmosphere packaging of the present invention substantially maintains its color during the shipping process because the package has a modified atmosphere in one embodiment that includes from about 0.1% to about 0.8 vol.% carbon monoxide. See DelDuca Decl. ¶ 8. In one method, after removal of the substantially impermeable layer, the CO is lost to the atmosphere. See page 12, lines 2-6 of the application; DelDuca Decl. ¶ 8. The CO may be lost to the atmosphere through the first layer that includes a portion that is substantially permeable to oxygen. *Id.* This allows the conversion of the carboxymyoglobin to oxymyoglobin by using the oxygen from the air. *Id.* The "gas mixture used in the modified atmosphere packages of the present invention, after removal, allows the carboxymyoglobin to convert to oxymyoglobin and then to metymyoglobin (brown) in a natural time period." *Id.*

II. General Law on Obviousness

The Supreme Court in KSR Int'l Co. v. Teleflex Inc., 127 S.Ct 1727 (2007) stated that the teaching, suggestion and motivation test is not to be rigidly applied, but did not apply a specific test to determine obviousness. Applying the KSR Int'l decision, the Federal Circuit in Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc. stated that "[a]n obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case." 485 F.3d 1157, 1161 (Fed. Cir. 2007). Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc. 127 S.Ct. at 1741.

Prior to the KSR Int'l Co. decision, the teaching, suggestion and motivation test stated that all the limitations of a claim must be taught or suggested by the combined prior art references. M.P.E.P. § 2143.03 (citing In re Royka, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974)). A prima facie case of obviousness requires three basic criteria:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P. § 2143.

Obviousness cannot "be established using hindsight or in view of the teachings or suggestions of the invention." Ex parte Maguire, No. 1999-1344, 2002 WL 1801466, at *4 (Bd. Pat. App. & Inter. 2002) (quoting Para-Ordnance Mfg. Inc. v. SGS Importers Int'l Inc., 73 F.3d 1085, 1087, 37 U.S.P.Q.2d 1237, 1239 (Fed. Cir. 1995), cert. denied, 519 U.S. 822 (1996)). Further, the proposed modification cannot render the prior art "unsatisfactory for its intended purpose" nor can it "change the principle of operation" of a reference. M.P.E.P. § 2143.01 (citing In re Gordon, 733 F.2d at 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984), and In re Ratti, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959)).

The law of obviousness requires that a reference be considered as a whole, including those portions that teach away from the claimed invention. *Armament Sys. & Procedures v. Monadnock Lifetime Prods.*, No. 97-1174, 1998 U.S. App. LEXIS 20818, at *23-24 (Fed. Cir. 1998); see also M.P.E.P. § 2141.02 (stating that prior art must be considered in its entirety including disclosures that teach away from the claims). Indicia of teaching away in a reference give insight into the question of obviousness. *Monarch Knitting Mach. Corp. v. Sulzer Morat GMBH*, 139 F.3d 877, 885, 45 U.S.P.Q.2d 1977, 1984 (Fed. Cir. 1998). A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Id.* (quoting *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994)).

The Examiner, of course, has the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under any statutory provision. *In re Mayne*, 104 F.3d 1339, 1341, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

For at least the reasons stated below, Appellants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness under 35 U.S.C. § 103 and requests reversal of the Examiner's 35 U.S.C. § 103 rejections.

III. A *Prima Facie* Case Has Not Been Presented With Respect To Independent Claims 38, 76, 119, 138 and 157 Using Stockley In View of Koch, Woodruff and Shaklai.

The pending independent claims (claims 38, 76, 119, 138 and 157) include, *inter alia*, (a) "a first layer having at least a portion being substantially permeable to oxygen"; (b) "a second layer being substantially impermeable to oxygen"; (c) a low oxygen environment that includes

from about 0.1 to about 0.8 vol.% CO; (d) the second layer being sealed to the package or the first layer, and (e) "wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer"; "opening the package such that the raw meat is allowed to be exposed to the ambient atmosphere and the carbon monoxide associated with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package or "opening the package before retail display such that the gas mixture exits the package and the carbon monoxide associated with the raw meat is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package." None of the applied references includes, *inter alia*, such limitations that are recited in independent claims 38, 76, 119, 138 and 157.

As acknowledged by the Examiner, U.S. Patent No. 5,686,127 to Stockley does <u>not</u> disclose, teach or suggest the use of CO. See page 3 of the Office Action dated August 12, 2005. The Examiner applies a number of references – Woodruff, Koch and Shaklai in an attempt to cure this deficiency in Stockley. These other references do not disclose a packaging system having, *inter alia*, (a) "a first layer having at least a portion being substantially permeable to oxygen"; and (b) "a second layer being substantially impermeable to oxygen" as recited in independent claims 38, 76, 119, 138 and 157.

It would not have been obvious to combine Stockley in view of other references such as Koch, Woodruff and/or Shaklai to arrive at the present invention. This erroneous conclusion by the Examiner ignores the understanding of those of ordinary skill in the art at the time of the present invention that CO "fixes" the color of the meat pigment and there would be <u>no</u> motivation to one of ordinary skill in the art for using CO in a modified atmosphere such as disclosed in Woodruff, Koch and/or Shaklai with a meat-packaging system such as disclosed in Stockley.

A. The Problems Of "Fixing" Color Are Known To Those Of Ordinary Skill In The Art

The problems of fixing meat color with CO, which can mask spoilage, are clearly known to those of ordinary skill in the art. See, e.g., Hunt Decl. ¶ 6 (Exhibit 5); DelDuca Second Decl. ¶ 4 (Exhibit 2). The problem of fixing meat color with CO was described in a previously applied

reference in this application to Sorheim et al.³ Furthermore, the United States Food and Drug Administration (FDA) has believed that the meat pigment color would be fixed using CO.⁴ Thus, the alleged "good" color (i.e., red color of fresh meat) disclosed in, for example, Woodruff is not a desirable attribute when the meat pigment remains such a color past its microbial soundness.

Thus, there is simply no motivation to combine Stockley with Woodruff, Koch and/or Shaklai in an attempt to address the problems solved by the present invention and to read on the pending claims.

B. The Applied References Of Shaklai, Koch And Woodruff Do Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Based on the strong submitted evidence from the Appellants that those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment at the time of the invention (i.e., that the meat pigment does not turn brown in a natural time period after the meat pigment is exposed to the atmosphere), the Examiner has attempted to apply a number of references allegedly stating otherwise. The Appellants will discuss these references and the reasons why they do not modify the belief before the Appellant's invention that CO "fixed" the color of the meat pigment.

Specifically, the Examiner states that: (a) "Shaklai and Koch . . . provide evidence that the packages of Stockley . . . will have CO [being] removably associate d with the meat in a natural time period"; and (b) "the art of record does show that meat exposed to CO will brown within a natural time period after removal of CO and exposure to normal atmosphere." Page 6 of the Office Action dated August 18, 2006.

In addition to not disclosing, teaching or suggesting the claimed first and second layers in the modified atmosphere package, none of the references of Shaklai, Koch or Woodruff, which

The applied reference was "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide" from *Meat Science* to Sorheim et al. ("Sorheim")(Exhibit 6), which was applied in the Office Action mailed on May 7, 2003. In particular, Sorheim disclosed that its meat packaging systems with a modified atmosphere of "0.4% CO/60% CO₂/40% N₂ had a bright stable red colour that lasted beyond the time of spoilage." (Underlining added). Abstract of Sorheim.

⁴ Exhibit 7 (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color", which was submitted in the Amendment and Response to Office Action Dated May 7, 2003); see also Hunt Decl. ¶ 6.

are individually discussed in detail below, teaches or suggests any of the claimed limitations of (a) "wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer"; (b) "opening the package such that the raw meat is allowed to be exposed to the ambient atmosphere and the carbon monoxide associated with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package" or (c) "opening the package before retail display such that the gas mixture exits the package and the carbon monoxide associated with the raw meat is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package." One of these limitations is specifically recited in independent claims 38, 76, 119, 138 and 157. Thus, there is no motivation to combine Shaklai, Koch and/or Woodruff with Stockley in the pending rejections.

i. Shaklai Teaches That CO "Fixes" The Color Of The Meat Pigment (I.e., Extends Color Life)

Since Shaklai teaches that CO "fixes" the color of the meat pigment after exposure to the atmosphere, there would be no motivation to one of ordinary skill in the art to combine Shaklai with Carr, Koch and Woodruff as in the pending rejections.

Specifically, Shaklai discloses exposing raw meat to an atmosphere consisting essentially of CO in which the meat is "completely immersed or saturated" with CO. See col. 5, lines 29-37. "More specifically, a cross-section of meat is completely immersed in or saturated to its core with carbon monoxide from the exposed surfaces through the entire cross-section (thickness) including its core region and retains the carbon monoxide until the meat is cooked. Thus, as stated above, the meat is preserved throughout its thickness." Col. 5, lines 38-43 of Shaklai.

Shaklai continues by stating that "[p]ractically all of the carbon monoxide (over 99.9%) taken up by meat will be maintained as hemoglobin and myoglobin (Hb/Mb) bound forms." Col. 5, lines 57-59. Shaklai also discloses that "[b]oth hemoglobin and myoglobin bind carbon monoxide much more strongly than oxygen." Col. 5, lines 66-67. "It is thought that the mechanism for carbon monoxide preserving of meat is the much greater affinity of myoglobin for carbon monoxide than for oxygen." Col. 6, lines 26-28 of Shaklai.

It is known to those of ordinary skill in the art that when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity 200 times greater than oxygen does with hemoglobin. Therefore, one of ordinary skill in the art would expect that CO "fixes" the color of the meat pigment past its natural time period upon exposure to the atmosphere. DelDuca Third Decl. ¶ 4 (Exhibit 3). In other words, because of the hemoglobin's high affinity towards CO, the pigment of the meat, prior to Appellants' invention, would not have been expected to degrade in a natural time period. *Id*.

The examples of Shaklai also support that the meat pigment is "fixed" beyond its natural time period. Specifically, Example 4 of Shaklai (mentioned at page 7 of the Office Action dated February 24, 2006) discloses that (a) meat treated with CO on day 14 had only a surface (less than 1 mm deep) being brown, while (b) meat treated with air was dark brown throughout. Col. 9, lines 40-50. Thus, it is clear that the meat pigment in Example 4 was "fixed" because it extended the color of meat pigment past its natural time period after being exposed to the atmosphere. This is further illustrated in Example 3 of Shaklai where the air-treated meat and CO-treated meat had different colors – the air-treated meat after 3 days was all brown and the CO-treated meat was a wine-red color. Col. 9, lines 10-19. Example 2 of Shaklai mentioned at page 7 of the Office Action dated February 24, 2006 also does not support that meat pigment is not "fixed" beyond its natural time period (air-treated samples were brown and CO-treated samples were a bright wine red after 24 hours). Col. 8, line 50-col. 9, line 5.

The Examiner asserts that Shaklai is being relied on as not fixing the color of the meat pigment surface. Pages 6-8 of the Office Action dated August 18, 2006; Page 7 of the Office Action dated February 24, 2006. This ignores the evidence in the above examples that Shaklai discloses that the color of the meat pigment is fixed. There is no expectation in Shaklai that by applying the CO levels disclosed in Woodruff that the meat would brown in a natural time period, let alone the "reasonable expectation of success" asserted by the Examiner. See page 6 of the Office Action dated August 18, 2006.

Thus, because Shaklai discloses "fixing" the color of the meat pigment, there would be no motivation to one of ordinary skill in the art to combine Shaklai with Stockley, Koch and

⁵ See, e.g., Color Atlas & Textbook of Hematology, Wm Platt, 2nd edition 1979 (Exhibit 8) submitted in Amendment and Reply to Final Office Action dated August 12, 2005; DelDuca Third Decl. ¶ 4 (Exhibit 3).

Woodruff as in the pending rejections because Shaklai discloses "fixing" the color of the meat pigment.

ii. Koch Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of its CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Shaklai and Woodruff as in the pending rejections.

Specifically, Koch discloses wrapping meat with a CO-containing film such that CO is transferred from the film to contact the surface of the meat. See abstract. An object of Koch is to include a relatively <u>small quantity of CO</u> that is gradually released from the CO-containing film. Col. 2, lines 18-22. Koch discloses (a) covering primal cuts made at a slaughterhouse with a CO-containing film, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc. Col. 3, lines 4-8.

First, Koch does not disclose the exact weight of the primal cuts of meat. "Primal" cuts of meat at the time of the Koch disclosure (late 1960's), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. DelDuca Third Decl. ¶ 7 (Exhibit 3). The term "subprimal" cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. *Id.* Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat. *Id.*

Second, the disclosure of Shaklai with 100% CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to 100% CO to turn the meat pigment to carboxymyoglobin. See col. 9, lines 11-28 of Shaklai and DelDuca Third Decl. ¶ 8. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-surface meat pigments to carboxymyoglobin. *Id*.

Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film. *Id.* It would be expected that the individually cut steaks and roasts sections of Koch that were not exposed to CO would degrade in a manner

similar to other similar cuts of steaks and roasts that had also <u>not</u> been exposed to CO. DelDuca Third Decl. ¶ 9. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts <u>not</u> exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. *Id.* Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film. *Id.*

In response to these arguments, the Examiner states that "Koch... each the use of their package for primal as well as the final cuts" and concludes that the "CO [is] removably associated with the meat in a natural time period." Page 8 of the Office Action dated August 18, 2006. This ignores the primal cuts to which Koch is directed, in which individual steaks and roast sections are not exposed to CO. Koch discloses "[w]hen the <u>primal cuts</u> arrive at the retail outlet, the covers are removed and the meat is cut into individual steaks, roasts, etc. which may be separately wrapped in conventional wrapping materials. It has been found that meat will release a saleable red color for as long as 10 days when covered with the cover herein described for the first seven days and with a conventional cover for the remaining days." Col. 3, lines 5-13 of Koch (underlining added); DelDuca Fourth Decl. ¶ 15 (Exhibit 4).

In summary, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film because it would <u>not</u> be reasonable that exposing a relatively <u>small quantity</u> of CO that is gradually released from the CO-containing film to a large quantity of meat (primal cuts) would expose CO to the non-surface meat pigments.

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Shaklai and Woodruff as in the pending rejections.

iii. Woodruff Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

The Examiner states that Woodruff "teach[es] that CO concentrations in the recited range of the applicant have been known to provide good color in meat during transportation and storage." Page 5 of the Office Action dated August 18, 2006. The Examiner continues by stating that "Woodruff [] teaches surface contact of a meat with CO to maintain a red color". *Id.* at page 6.

Woodruff does not teach or suggest that the color of the meat pigment turns brown in a natural time period. DelDuca Fourth Decl. ¶ 12 (Exhibit 4). For example, Woodruff in Example 1 discloses a 0.5 lb. beefsteak that was exposed to 0.5% CO, which was nearly all absorbed two days later. See col. 4, lines 34-48; DelDuca Fourth Decl. ¶ 12. After being exposed in a modified atmosphere that included 16% oxygen, "the beefsteak retained its good red color, and the carboxymyoglobin color had penetrated no more deeply than it had at the end of the two days." See col. 4, lines 49-54. This passage implies that the carboxymyoglobin color was still retained within the beefsteak after 6 days despite being exposed to an atmosphere with a generally similar amount of oxygen as in air (compare about 21% oxygen to 16% oxygen). DelDuca Fourth Decl. ¶ 12. It would be expected to one skilled in the art that the beefsteak would turn brown in about 2-3 days, depending on the cut of meat. *Id.* Thus, this example clearly shows that the beefsteak of Woodruff in Example 1 did not turn brown in a natural time period, but rather "fixed" the color of the meat pigment. *Id.* Similarly, in Example 1 of Woodruff, a 0.5 lb. beefsteak exposed to 2.5% CO under similar conditions also retained its good color after 6 days. See col. 4, line 55- col. 5, line 6; DelDuca Fourth Decl. ¶ 12.

None of the other examples of Woodruff supports a modified atmosphere package wherein the CO associated with the raw meat is adapted to be removed such that the color of the meat pigment is not fixed and turns brown in a natural time period. DelDuca Fourth Decl. at ¶ 13. Rather, the other examples of Woodruff generally disclose the condition of the meat pigment while being stored in a modified atmosphere containing CO. *Id.* In summary, Woodruff does not disclose, teach or suggest that the use of CO on meat pigment turns brown in a natural time period, but rather Woodruff teaches and suggests "fixing" the color of the meat pigment in Example 1. *Id.* at 14.

Since Woodruff does not teach or suggest that the use of CO turns meat pigment brown in a natural time period, there would be no motivation to one of ordinary skill in the art to combine Woodruff with Stockley, Shaklai and Koch as in the pending rejections.

Thus, for at least the reasons discussed above, the Appellants believe that a *prima facie* case has not been presented with Stockley, Woodruff, Koch, Shaklai or any combination thereof with respect to independent claims 38, 76, 119, 138 and 157 or dependent claims 40-56, 78-86, 121, 123-137, 140, 142-156, 159 and 161-168.

IV. A *Prima Facie* Case Has Not Been Presented With Respect To Dependent Claims 39, 77, 120, 139 and 158 Using Stockley In View of Koch, Woodruff, Shaklai And Garwood.

Claims 39, 77, 120, 139 and 158 depend on independent claim 36, 76, 119, 138 or 157. For at least the same reasons as discussed above with respect to independent claims 36, 76, 119, 138 or 157, it would not have been obvious to combine Stockley in view of other references such as Koch, Woodruff, Shaklai, Garwood and/or to arrive at the present invention. Garwood does not teach or suggest the use of CO turns meat pigment in a natural time period. Thus, Garwood does not address the deficiencies discussed above. Thus, for at least the reasons discussed above, the Appellants believe that a *prima facie* case has not been presented with Stockley, Woodruff, Koch, Shaklai, Garwood or any combination thereof with respect to dependent claims 39, 77, 120, 139 and 158.

V. Evidence of Non-Obviousness of Independent Claims 38, 76, 119, 138 and 157

Assuming, *arguendo*, that a *prima facie* case has been presented (which Appellants strongly believe is not the case), the Appellants previously submitted evidence of non-obviousness including the DelDuca Declarations (Exhibits 1-4) and the Hunt Declaration (Exhibit 5). Secondary consideration such as long felt but unsolved needs, failure of others, etc. may be used to give light to the circumstances surrounding the origin of the subject and, thus, may be used to rebut a *prima facie* case of obviousness. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

A. CO Not Allowed With Fresh Meat In The United States Since At Least 1962

Carbon monoxide (CO) has not been allowed to be used with fresh meat in the United States for about 40 years.^{6,7} The Food and Drug Administration ("FDA") regulation that currently prevents using CO with meat-packaging systems in the United States is 21 C.F.R. § 173.350.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen...(b) The food additive meets the following specifications: (1) Carbon monoxide content not to exceed 4.5 percent by volume...(c) It [carbon monoxide] is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

Exhibit 11 (emphasis added); see also DelDuca Decl. ¶ 9 (Exhibit 1).

The concern of the FDA is believed to be that CO fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is unsafe and potentially dangerous to consume because it has unacceptable levels of bacteria. DelDuca Decl. ¶ 10 (Exhibit 1).8 This act of fixing the meat color to a bright red color is referred to as "economic adulteration." *Id.*

B. CO Now Allowed In Pactiv's Novel Approaches

After about 40 years of not allowing CO to be used with fresh meats in the United States, the Appellants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of "fixing" the meat color. DelDuca Second Decl. ¶ 4 (Exhibit 2).

⁶ 21 U.S.C. § 121.1060 was first promulgated on August 2, 1961 (Exhibit 9) and permitted the use of combustion product gas containing up to 4.5% CO for use "to displace or remove oxygen or remove oxygen in the processing, storage, or packaging of citrus products, vegetable fats and vegetable oils, coffee, and wine." In December 14, 1962, 21 U.S.C. § 121.1060 (Exhibit 10) was amended to exclude fresh meats. In March of 1977, 21 U.S.C. § 121.1060 was re-designated as 21 C.F.R. § 173.350. Both Exhibits 9 and 10 were submitted in the Amendment and Response to Office Action Dated May 7, 2003. ⁷ See also DelDuca Decl.¶ 9.

⁸ See, e.g., Exhibit 7 (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.")

i. One Novel Pactiv Approach⁹

One of the novel approaches invented by the Appellants that avoids the concerns of fixing the color of the meat pigment involved using a specific MAP system that was presented in a GRAS notice ("Pactiv's improved ActiveTech® meat packaging system"). Pactiv's improved ActiveTech® meat packaging system included meats being placed in polystyrene trays and covered with oxygen-permeable, polyvinyl chloride ("PVC") overwraps. DelDuca Second Decl. ¶ 5. The wrapped trays of meat are then placed in an outer barrier bag. *Id.* Ambient air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide, and the balance being nitrogen. *Id.*

Dr. Hunt, who has extensive experience in the processing of meat using modified atmosphere packaging, stated that "[t]he results of the testing [of the Pactiv's improved ctiveTech® meat packaging system] were surprising to me because it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red." Hunt Decl. ¶ 6 (Exhibit 5). Pactiv's improved ActiveTech® meat packaging system using 0.4 vol.%, however, did not fix the color of the meat pigment as expected and Dr. Hunt stated that "[t]his was a novel result and was not at all obvious due to the current and long standing thought that meat exposed to CO would develop a color that would mask spoilage." *Id*.

The FDA stated that it had no questions regarding Pactiv's conclusion about Pactiv's improved ActiveTech® meat packaging system using 0.4% CO being GRAS because of the evidence presented by Pactiv in its GRAS notice. DelDuca Second Decl. ¶ 6 (Exhibit 2); Exhibit 12¹⁰. This FDA review allows Pactiv to use CO with fresh meat in its application. *Id.* It is believed to be the first system to overcome the prohibition of CO with fresh meat in the United States in the last 40 years. *Id.*

ii. Another Novel Pactiv Approach

Besides Pactiv's improved ActiveTech® meat packaging system, the Appellants invented other novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoid the concerns of "fixing" the meat color. Some of these other novel approaches include low

⁹ This novel approach is the subject of other patent applications.

Exhibit 12 was originally submitted as an exhibit to the DelDuca Second Declaration, which was filed in the Amendment & Reply to Office Action Dated June 14, 2004.

oxygen environment, meat packaging systems having (a) a first layer being a substantially permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture including 0.4 vol.% CO.

An example of a low oxygen environment, meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a "peelable" system. DelDuca Second Decl. ¶ 8 (Exhibit 2). A peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. *Id.* The first layer is located closest to the meat, while the second layer is located farthest from the meat. *Id.* The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the substantially permeable first layer. *Id.*

The process of manufacturing the above-described peelable system is one example of a process that would be covered by independent claims 38, 119 and 138 of the present application. *Id.* at \P 9. The above-described peelable system is one example of modified atmosphere packaging that would be covered by independent claims 76 and 157 of the present application. *Id.*

It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. DelDuca Second Decl. ¶ 9; Hunt Decl. ¶ ¶ 7-9. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap). DelDuca Second Decl. ¶ 9; Hunt Decl. ¶ 9.

Cryovac makes such a peelable system using 0.4 vol.% CO under the name Darfresh®. DelDuca Second Decl. ¶ 11. Cryovac in its GRAS notice represented that the Cryovac package "allow[s] the meat pigment color to change over time as though it has not been exposed to CO." See DelDuca Second Decl. ¶ 11; Exhibit 13¹¹. As a result, the "FDA concluded that Cryovac's MAP system fell within the scope of GRAS Notice No. GRN 00083 [which is directed to Pactiv's improved ActiveTech® meat packaging system]." *Id.* Thus, both Cryovac and the FDA believe that such a peelable system using 0.4 vol.% CO would not fix the color of the meat pigment to red.

¹¹ Exhibit 13 was originally submitted as an exhibit to the DelDuca Second Declaration, which was filed in the Amendment & Reply to Office Action Dated June 14, 2004.

Dr. Hunt also stated that he believed "that the surprising results obtained in the testing of Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO would be equally applicable" to methods such as the peelable system described above. Hunt Decl. ¶ 7.

Thus, a problem of fixing meat color with CO that was recognized for at least the last 40 years was overcome by various inventive embodiments/methods of the Appellants including (a) Pactiv's improved ActiveTech® meat packaging system and process of manufacturing the same; and (b) a peelable meat packaging system described above and process of manufacturing the same, which is an example of a system and a process that would be covered by the independent claims of the present application. Additionally, such results were surprising to one skilled in the art (Dr. Hunt) in that they did not fix the color of the meat pigment to red.

C. Pactiv's Novel Meat-Packaging Systems and Processes Using CO Address a Long-Felt Need

The Federal Circuit has stated that if an invention unexpectedly solved longstanding problems, it supports the conclusion of nonobviousness. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1382 (Fed. Cir 1986); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

Pactiv's novel meat-packaging systems and methods of manufacturing the same are examples of systems and processes that addressed such a long-felt need. More specifically, both (a) Pactiv's improved ActiveTech® meat packaging system and (b) a peelable meat-packaging system described above and process of the same, which is an example of a system and a process that would be covered be independent claims of the present application, addressed such a long-felt need in the meat-packaging industry. "Prior to Pactiv's novel meat packaging approaches using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product." See Hunt Decl. ¶¶10, 11. "Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations." See id. Pactiv's novel meat packaging systems using 0.4 vol.% CO were new and novel approaches that addressed these technological needs." See id.

Thus, since Pactiv's novel meat packaging systems using 0.4 vol.% CO surprisingly addressed a long-felt need, this is further evidence that the independent claims of the present application are not obvious over the applied references.

In response to this evidence on long-felt need, the Examiner asserted that "[i]t is notoriously well known in the art [from the applied references] that a red colored meat at the retail outlet is most desired. It was also known that meat exposed to CO in a modified atmosphere environment would provide the meat with a red color after the meat was removed from the modified atmosphere environment." Page 11 of the Office Action dated August 18, 2006. This clearly ignores the understanding of those skilled in the art prior to Appellant's invention that CO "fixed" the color of the meat pigment, which is discussed in detail above.

Therefore, in addition to the applied references not presenting a *prima facie* case, the Appellants also believe that the pending claims are allowable because of the compelling evidence of non-obviousness. Therefore, independent claims 38, 76, 119, 138 and 157 are not obvious in view of Stockley, Woodruff, Koch, Shaklai or any combination thereof and, thus, should be in a condition for allowance. Additionally, dependent claims 39-56, 77-86, 120, 121, 123-137, 139, 140, 142-156, 158, 159 and 161-168 are not obvious in view of Stockley, Woodruff, Koch, Shaklai, Garwood or any combination thereof and, thus, should be in a condition for allowance for at least the same reasons. The Appellants request reversal of the Examiner's 35 U.S.C. § 103 rejections.

8. CONCLUSION

For the reasons set forth above, Appellants respectfully submit that the Examiner's rejections fail to present a *prima facie* case of obviousness under 35 U.S.C. § 103. Additionally, even if a *prima facie* case has been presented (which Appellants strongly believe is not the case), the overwhelming evidence of non-obviousness rebuts any *prima facie* case of obviousness. Based upon the arguments submitted above, Appellants respectfully solicit the reversal of the Examiner's 35 U.S.C. § 103 rejections of claims 38-56, 76-86 and 119-168 on at least the grounds noted above.

The Appellants note that the fee of \$500.00 required by 37 C.F.R. §41.20(b)(1) has already been paid. The Appellants request that the fee of \$500.00 for the Notice of Appeal filed under 37 C.F.R. §41.20(b)(2) be deducted from Nixon Peabody LLP Deposit Account No. 50-

4181 (247097-001106USPT). The Commissioner is also hereby authorized to charge deposit account No. 50-4181 (Attorney Docket No. 247097-001106USPT) for any additional fees inadvertently omitted which may be necessary now or during the pendency of this application, except for the issue fee.

<u>August 31, 2007</u> Date Respectfully submitted,

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9.	RELATED	PROCEEDINGS	APPENDIX

None

10. APPENDIX OF CLAIMS ON APPEAL

Listing of Claims:

- 1-37 Cancelled.
- 38. A method of manufacturing a modified atmosphere package, the method comprising:
 - supplying a package, a first layer having at least a portion being substantially permeable to oxygen and a second layer being substantially impermeable to oxygen;

placing a retail cut of raw meat within the package, the meat having meat pigment;

- supplying a mixture of gases within the package, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;
- removing oxygen within the package so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat;

sealing the first layer to the package; and

- sealing the second layer to at least one of the group consisting of the package and the first layer, the second layer being adapted to be removed such that the second layer is no longer sealed to the package or the first layer, the first layer remains sealed to the package, and wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer.
- 39. The method of claim 38, wherein a pocket is formed between the first layer and the second layer.

- 40. The method of claim 38, wherein the second layer is at least sealed to the first layer and the second layer is adapted to be peelable from the first layer.
- 41. The method of claim 38, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects generally laterally outwardly therefrom.
 - 42. The method of claim 38 further including removing the second layer.
 - 43. The method of claim 38 further including supplying an oxygen scavenger.
- 44. The method of claim 38, wherein the oxygen level in the package is less than 1,000 ppm.
- 45. The method of claim 44, wherein the oxygen level in the package is less than about 500 ppm.
- 46. The method of claim 38, wherein removing oxygen from the package includes evacuating the package.
- 47. The method of claim 38, wherein removing oxygen from the package includes flushing the package with the gas mixture.
- 48. The method of claim 38, wherein the gas mixture further comprises nitrogen, carbon dioxide or the combination thereof.
- 49. The method of claim 38, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

- 50. The method of claim 38, wherein the gas mixture consists of from about 0.1 vol.% to about 0.6 vol.% carbon monoxide with the remainder carbon dioxide.
- 51. The method of claim 38 further including placing the retail cut of raw meat on a foam tray.
- 52. The method of claim 38, wherein the portion being substantially permeable to oxygen comprises a polyolefin or a polyvinyl chloride overwrap.
- 53. The method of claim 38, wherein the gas mixture is supplied to the package such that the oxymyoglobin substantially converts directly to carboxymyoglobin.
- 54. The method of claim 38, wherein the oxymyoglobin substantially converts to deoxymyoglobin before the gas mixture is supplied to the package so as to convert deoxymyoglobin directly to carboxymyoglobin.
- 55. The method of claim 38, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.
- 56. The method of claim 38, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

57-75. Cancelled.

- 76. A modified atmosphere package, comprising:
- a package being configured and sized to fully enclose a retail cut of raw meat, the meat having meat pigment, the package having a mixture of gases comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

- a first layer having at least a portion being substantially permeable to oxygen and sealed to the package; and
- a second layer being substantially impermeable to oxygen and sealed to at least one of the group consisting of the package and the first layer, the second layer being adapted to be removed such that the second layer is no longer sealed to the package or the first layer, and the first layer remains sealed to the package, and wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer.
- 77. The package of claim 76, wherein a pocket is formed between the first layer and the second layer.
- 78. The package of claim 76, wherein the second layer is at least sealed to the first layer, the second layer being adapted to be peelable from the first layer.
- 79. The package of claim 76, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects laterally outwardly therefrom.
 - 80. The package of claim 76 further including supplying an oxygen scavenger.
- 81. The package of claim 76, wherein the oxygen level in the package is less than 1,000 ppm.
- 82. The package of claim 81, wherein the oxygen level in the package is less than about 500 ppm.

- 83. The package of claim 76, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.
- 84. The package of claim 77, wherein the package further includes a foam tray sized to hold the meat.
- 85. The package of claim 77, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.
- 86. The package of claim 77, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

87-118. Cancelled

119. A method of manufacturing a modified atmosphere package, the method comprising:

supplying a package, a first layer having at least a portion being substantially permeable to oxygen and a second layer being substantially impermeable to oxygen;

placing a retail cut of raw meat within the package, the meat having meat pigment;

supplying a mixture of gases within the package, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

removing oxygen within the package so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat;

sealing the first layer to the package;

sealing the second layer to at least one of the group consisting of the package and the first layer; and

opening the package such that the raw meat is allowed to be exposed to the ambient

atmosphere and the carbon monoxide associated with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package.

- 120. The method of claim 119, wherein a pocket is formed between the first layer and the second layer.
- 121. The method of claim 119, wherein the second layer is at least sealed to the first layer, the second layer being peeled from the first layer such that the raw meat is allowed to be exposed to the ambient atmosphere through the second layer.
- 122. The method of claim 119, wherein the second layer is at least sealed to the package and the second layer is peeled from the package such that the raw meat is allowed to be exposed to the ambient atmosphere through the second layer.
- 123. The method of claim 119, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects generally laterally outwardly therefrom.
 - 124. The method of claim 119 further including supplying an oxygen scavenger.
- 125. The method of claim 119, wherein the oxygen level in the package is less than 1,000 ppm.
- 126. The method of claim 125, wherein the oxygen level in the package is less than about 500 ppm.
- 127. The method of claim 119, wherein removing oxygen from the package includes evacuating the package.

- 128. The method of claim 119, wherein removing oxygen from the package includes flushing the package with the gas mixture.
- 129. The method of claim 119, wherein the gas mixture further comprises nitrogen, carbon dioxide or the combination thereof.
- 130. The method of claim 119, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.
- 131. The method of claim 119, wherein the gas mixture consists of from about 0.1 vol.% to about 0.6 vol.% carbon monoxide with the remainder carbon dioxide.
- 132. The method of claim 119 further including placing the retail cut of raw meat on a foam tray.
- 133. The method of claim 119, wherein the portion being substantially permeable to oxygen comprises a polyolefin or a polyvinyl chloride overwrap.
- 134. The method of claim 119, wherein the gas mixture is supplied to the package such that the oxymyoglobin substantially converts directly to carboxymyoglobin.
- 135. The method of claim 119, wherein the oxymyoglobin substantially converts to deoxymyoglobin before the gas mixture is supplied to the package so as to convert deoxymyoglobin directly to carboxymyoglobin.
- 136. The method of claim 119, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.
- 137. The method of claim 119, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

- 138. A method of manufacturing a modified atmosphere package, the method comprising:
 - supplying a package, a first layer having at least a portion being substantially permeable to oxygen and a second layer being substantially impermeable to oxygen;

placing a retail cut of raw meat within the package, the meat having meat pigment;

- supplying a mixture of gases within the package, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;
- removing oxygen within the package so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat;

sealing the first layer to the package;

- sealing the second layer to at least one of the group consisting of the package and the first layer; and
- opening the package before retail display such that the gas mixture exits the package and the carbon monoxide associated with the raw meat is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package.
- 139. The method of claim 138, wherein a pocket is formed between the first layer and the second layer.
- 140. The method of claim 138, wherein the second layer is at least sealed to the first layer, and the opening of the package includes removing the second layer from the first layer before retail display such that the gas mixture exits the package through the first layer.
- 141. The method of claim 138, wherein the second layer is at least sealed to the package and the opening of the package includes removing the second layer from the package before retail display such that the gas mixture exits the package through the first layer.

- 142. The method of claim 138, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects generally laterally outwardly therefrom.
 - 143. The method of claim 138 further including supplying an oxygen scavenger.
- 144. The method of claim 138, wherein the oxygen level in the package is less than 1,000 ppm.
- 145. The method of claim 144, wherein the oxygen level in the package is less than about 500 ppm.
- 146. The method of claim 138, wherein removing oxygen from the package includes evacuating the package.
- 147. The method of claim 138, wherein removing oxygen from the package includes flushing the package with the gas mixture.
- 148. The method of claim 138, wherein the gas mixture further comprises nitrogen, carbon dioxide or the combination thereof.
- 149. The method of claim 138, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.
- 150. The method of claim 138, wherein the gas mixture consists of from about 0.1 vol.% to about 0.6 vol.% carbon monoxide with the remainder carbon dioxide.

- 151. The method of claim 138 further including placing the retail cut of raw meat on a foam tray.
- 152. The method of claim 138, wherein the portion being substantially permeable to oxygen comprises a polyolefin or a polyvinyl chloride overwrap.
- 153. The method of claim 138, wherein the gas mixture is supplied to the package such that the oxymyoglobin substantially converts directly to carboxymyoglobin.
- 154. The method of claim 138, wherein the oxymyoglobin substantially converts to deoxymyoglobin before the gas mixture is supplied to the package so as to convert deoxymyoglobin directly to carboxymyoglobin.
- 155. The method of claim 138, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.
- 156. The method of claim 138, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.
 - 157. A modified atmosphere package, comprising:
 - a package being configured and sized to fully enclose a retail cut of raw meat, the meat having meat pigment, the package having a mixture of gases comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;
 - a first layer having at least a portion being substantially permeable to oxygen and sealed to the package; and
 - a second layer being substantially impermeable to oxygen and sealed to at least one of the group consisting of the package and the first layer,
 - wherein the package is adapted to be opened such that the raw meat is allowed to be exposed to the ambient atmosphere and wherein the carbon monoxide associated

with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package.

- 158. The package of claim 157, wherein a pocket is formed between the first layer and the second layer.
- 159. The package of claim 157, wherein the second layer is at least sealed to the first layer, the second layer being adapted to be removed from the first layer such that the raw meat is allowed to be exposed to the ambient atmosphere.
- 160. The package of claim 157, wherein the second layer is at least sealed to the package and the second layer is adapted to be removed from the package such that the raw meat is allowed to be exposed to the ambient atmosphere.
- 161. The package of claim 157, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects laterally outwardly therefrom.
 - 162. The package of claim 157 further including supplying an oxygen scavenger.
- 163. The package of claim 157, wherein the oxygen level in the package is less than 1,000 ppm.
- 164. The package of claim 157, wherein the oxygen level in the package is less than about 500 ppm.
- 165. The package of claim 157, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

- 166. The package of claim 157, wherein the package further includes a foam tray sized to hold the meat.
- 167. The package of claim 157, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.
- 168. The package of claim 157, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

11. EVIDENCE APPENDIX

Exhibit 13 – FDA letter to Cryovac

Exhibit 1 – Declaration of Mr. Gary DelDuca Second Declaration of Mr. Gary DelDuca Exhibit 2 – Exhibit 3 – Third Declaration of Mr. Gary DelDuca Exhibit 4 – Fourth Declaration of Mr. Gary DelDuca Exhibit 5 – Declaration of Dr. Melvin C. Hunt Curriculum Vitae of Dr. Melvin C. Hunt Exhibit A – Exhibit B – Pactiv GRAS Notice Exhibit 6 – "The Storage Life Of Beef And Pork Packaged In An Atmosphere With Low Carbon Monoxide And High Carbon Dioxide" by Sorheim et al. 1962 letters between FDA and Whirlpool Corporation Exhibit 7 – Color Atlas & Textbook of Hematology, Wm Platt, 2nd edition 1979 Exhibit 8 – 21 U.S.C. § 121.1060 dated August 2, 1961 Exhibit 9 – 21 U.S.C. § 121.1060 dated December 14, 1962 Exhibit 10 – Exhibit 11 – 21 C.F.R. § 173.350 FDA No Questions Letter from 2002/2003 to Pactiv from Eric Greenberg Exhibit 12 –